Request for permission for oral testimony at Idaho Medicaid's P&T Committee meeting on 04-15-2011

Submission # 9

The following request has been:

- ○ Approved
- ☒ Denied

Gennrich, Jane - Medicaid

From: Eide, Tamara J. - Medicaid
Sent: Tuesday, March 15, 2011 8:21 AM
To: Gennrich, Jane - Medicaid
Subject: FW: 4/15/2011 P&T testimony
Attachments: Vesicare (Astellas) Idaho P and T April 15 2011 v2 .docx

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From: Shull, Toni [mailto:Toni.Shull@us.astellas.com]
Sent: Monday, March 14, 2011 6:08 PM
To: Eide, Tamara J. - Medicaid
Subject: FW: 4/15/2011 P&T testimony

Dear Dr. Eide,

Please delete the previous version of my proposed testimony and utilize the attached version for your review. I discovered reference errors and have since corrected them. I apologize for any inconvenience.

Sincerely,

Toni

Toni Shull, RN
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From: Shull, Toni

Sent: Monday, March 14, 2011 4:14 PM
To: 'eidet@dhw.idaho.gov'
Cc: Case, David; Platte, Leigh
Subject: 4/15/2011 P&T testimony

Dear Dr. Eide,

I will be providing testimony on behalf of Vesicare at your April 15, 2011 P&T Committee meeting. I have attached the script for your review and consideration. Should you have questions or require anything further, please feel free to contact me by email or my cell# 714 307 7886.

Thank you,

Toni

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VESIcare (solifenacin succinate): Preferred Drug List
Idaho Medicaid Formulary Review, April 15, 2011

This presentation is in response to an unsolicited request for scientific data. The information provided is for scientific exchange and in not intended to recommend administration of VESIcare in a manner inconsistent with approved labeling.

• VESIcare tablets are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency..[1]
• The recommended dose of VESIcare is 5 mg once daily. If the 5mg dose is well tolerated, the dose may be increased to 10 mg once daily
• VESIcare has been evaluated in four Ph 3a and five Ph 3b/4 randomized control trials and three open-label trials investigating efficacy regarding key OAB symptoms and patient-reported outcomes.

VECTOR
The VECTOR study (randomized, double-blind, double-dummy, 8 week trial with 132 subjects) compared the tolerability (primary) and efficacy (secondary) of 5 mg solifenacin once daily and 5 mg oxybutynin IR three times daily. [2]
o Solifenacin treatment was associated with significantly fewer dry mouth episodes and significantly less dry mouth severity, as compared to oxybutynin IR. Solifenacin was also associated with lower rates of adverse events and lower severity overall.
o Adverse events in patients taking solifenacin and oxybutynin included dry mouth (35%, 83%), constipation (13%, 6%), and nasal dryness (0%, 14%), respectively. Both solifenacin and oxybutynin IR significantly reduced symptoms and improved patient-reported outcomes.
VECTOR YOUNG/OLD
A post hoc analysis was conducted comparing outcomes in patients who were ≤ 65 years old and those patients ≥ 65 years old. The incidence and severity of dry mouth and other adverse events were similar between younger and older subgroups. Solifenacin 5 mg/day was associated with fewer episodes and lower severity of dry mouth, and a lower discontinuation rate, compared with oxybutynin IR 15mg per day. [3]

VERSUS
In the VERSUS (12 week, open-label, flexible-dose) trial, the efficacy of solifenacin was studied in patients who had been treated with tolterodine ER 4 mg for ≥4 weeks and still experienced residual urgency.[4] Baseline data were obtained prior to tolterodine discontinuation. The trial design was 12-weeks, with pre-washout, post-washout, 1 week, 4, 8 and 12 week data.
o After a 14-day washout period, solifenacin (5 or 10 mg) significantly reduced the number of daily urgency episodes (median percent reduction of 75% from pre-washout to end of study). o Solifenacin significantly improved diary variables (micturitions, incontinence episodes, nocturia episodes, nocturnal voids) and OAB-q bother and individual domains compared to pre- and post-washout.

o Treatment-emergent adverse events included dry mouth (17.5%), constipation (11.6%), blurred vision (2.3%) and headache (2.9%), and at rates similar to that reported in previous trials.

VERSUS SEVERE

In a post-hoc analysis of VERSUS severe patients, solifenacin treatment resulted in a median percent decrease from pre-washout to study end of 69.2% for urgency episodes, 15.2% for number of micturitions, 83.3% for incontinence episodes, 55.6% for nocturia episodes and 40.0% for nocturnal voids. In the VERSUS severe subset, treatment-emergent adverse events included dry mouth (16.4%), constipation (6.9%) and blurred vision (0.9%). [5]

VERSUS ELDERLY

In an exploratory *post-hoc* analysis of the VERSUS trial, two elderly cohorts (108 pts 65-74 yrs of age, and 86 pts >74 yrs of age) receiving 5 or 10 mg of VESIcare daily experienced significantly improved health-related quality of life, reduced activity impairment and fewer non-protocol related office visits. [6] These findings parallel those reported for the full analysis set.

VOLT

This 12-week,prospective, multicenter, open-label, flexible dose study evaluated the efficacy solifenacin 5 or 10 mg by improvement/satisfaction in the Patients Perception of Bladder Condition (PPBC) scale and by a visual analog scale (VAS). [8]

o Flexible dosing of VESIcare 5 and 10 mg daily was associated with significant reductions on PPBC (mean baseline 4.4 to mean EOT 2.9, $p<0.001$) and in patient-reported symptom bother (VAS) and HRQL.

VOLT MBS

o A post-hoc analysis of over 2,225 subjects enrolled in VOLT (12 week, flexible dose VESIcare Open-Label Trial) reported significant improvements in patient reported outcomes of frequency, urgency, urge incontinence and nocturia. [9]

o Subjects reported symptom-related bother with a visual analog scale, stratified according to most bothersome symptom (frequency, urgency, urge incontinence or nocturia).

o Stratified improvements were: 43.9%, nocturia; 51.7%, urge incontinence; 44.5%, urgency; 46.3%,frequency. o Treatment-emergent adverse events varied according to most bothersome symptom, and included dry mouth (17.9-27.7%), constipation (12.4-14.6%), and blurred vision (2.1-3.4%).

VOLT ACUTE/EARLY CHRONIC/LATE CHRONIC

A post hoc analysis compared the effect of solifenacin in patients who had different overactive bladder symptom duration; acute (three months to one year), early chronic (one to five years), and late chronic (five years or more). Results showed that irrespective of overactive bladder symptom duration, patients who received 12 weeks of solifenacin therapy perceived meaningful improvements in symptom-specific bother, health-related quality of life, and overall bladder condition.[10]

VERSUS/VOLT (PROs Men)
In the VERSUS trial (12 week, open-label, flexible-dose), the efficacy of solifenacin was studied in patients who had been treated with tolterodine ER 4 mg for ≥4 weeks and still experienced residual urgency. VOLT was a 12-week, prospective, multicenter, open-label, flexible dose study evaluating the efficacy of solifenacin 5 or 10 mg by improvement/satisfaction in the perception of bladder condition (PBC) scale and by a visual analog scale (VAS).
A *post hoc* analysis of men without presumed BOO from these two large open label studies showed that after 12 weeks of solifenacin, mean scores on the Patient Perception of Bladder Condition (PPBC) and mean scores on the OABq were significantly improved. Solifenacin significantly improved the Patient Reported Outcome (PRO) measures of symptom bother, health-related quality of life, and overall perception of bladder problems.[11]

References

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